REMARKS

Claims 13-18, 20-22, 25, and 28-30 are pending in the present application. Claims 13-18, 20-22, 25, and 28-30 read on the elected invention.

The rejection of Claims 13-22, 25, and 27 under 35 U.S.C. §112, first paragraph (written description), is respectfully traversed.

In the outstanding Office Action the Examiner asserts that Applicants arguments set forth on April 20, 2006 are not persuasive. In stating his basis for this assertion, the Examiner alleges that:

> The instant invention, unlike *Capon,* is directed toward methods using genetically altered microorganisms belonging to the genus *Escherichia* to produce any purine nucleoside, where the altered microorganisms are modified to block a reaction catalyzed by phosphoglucose isomerase. The specific mutations to the gene encoding phosphoglucose isomerase resulting in any microorganism having the ability to overproduce any purine nucleoside compared to an untransformed microorganism have not been described by the specification as being well-known in the art. This contrasts with *Capon* which involves chimeric genes used in gene therapy. Thus, the conclusions reached from *Capon* are not applicable to the instant invention.

In making this assertion the Examiner completely disregards the import an holding of *Capon* apparently taking the position that *Capon* is limited to chimeric genes used in gene therapy, but does not apply to any other use of a well-known gene. This is certainly not the case. In *Capon*, the Court held that the "written description" requirement must be applied in the context of the particular invention and the state of the knowledge in the art. Such a holding clearly applies beyond the context of chimeric genes used in gene therapy.

Moreover, in *Capon*, the Court held that when the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh. Therefore, where a person experienced in the field of this invention would know that

the DNA of the claims is well-known, *there is no requirement to once again set forth these sequences*. This holding is not restricted to the context of chimeric genes used in gene therapy.

This *fact* is further evidenced by the Federal Circuit's conclusions in *Falkner et al v. Inglis et al*, 79 USPQ2d 1001(Fed. Cir. 2006) (a copy is **submitted herewith**) in which the Federal Circuit summarized and clarified the "written description" requirement in the biotechnical context. In clarifying the written description standard in *Falkner*, the Federal Circuit held that for purposes of the written description requirement, "(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." Clearly, the Federal Circuit intends the written description requirement account for the fact that the specification is written for the skilled artisan, and it is thus unnecessary to spell out every detail when the skilled artsian would readily be convinced that the applicant possessed the invention. The *Falkner* Court also reasoned that when accessible literature sources clearly provide the structure of a biological macromolecule, a re-description of what is already known is not necessary.

Applicants again submit that the sequences underlying the terms "succinyl-adenosine monophosphate synthase, purine nucleoside phosphorylase, adenosine deaminase, inosine-guanosine kinase, guanosine monophosphate reductase, 6-phosphogluconoate deydrase, phosphoglucose isomerase, adenine deaminase, and xanthosine phosphorylase" in *Escherichia* were known in the art at the time of the present invention as evidenced by Blattner et al, *Science* 277, 1453-1462 (1997) (copy submitted with the response filed on

April 20, 2006). Blattner et al placed the public in possession of the complete genomic nucleotide sequence of E. coli. Further, the polynucleotide and encoded polypeptide sequences were publicly available via the GenBank sequence data based as of the date of the present invention. Thus, the sequences of the present invention were *per se* known in the art as of the date of the present invention. As such, precedent of *Capon* and *Falkner* make it clear that it is not necessary for Applicants to again spell out the specific sequences to comply with the written description requirement.

In view of the foregoing, Applicants submit that the presently claimed invention complies with the written description requirement of 35 U.S.C. §112, first paragraph. Therefore, withdrawal of this ground of rejection is requested.

The rejection of Claim 16 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Applicants have amended Claim 16 to specifically address the Examiner's criticism. Accordingly, this ground of rejection is believed to be moot.

Withdrawal of this ground of rejection is requested.

The objection of Claims 13-18, 20-22, 25, and 27 as reciting non-elected subject matter is obviated by amendment. Withdrawal of this ground of rejection is requested..

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Stephen G. Baxter, Ph.D.
Attorney of Record
Registration No. 32,884

Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number
22850
(703) 413-3000
Fax #: (703)413-2220

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Falkner v. Inglis, 79 USPQ2d 1001 (Fed. Cir. 2006)

79 USPQ2d 1001
Falkner v. Inglis
U.S. Court of Appeals
Federal Circuit
No. 05-1324
Decided May 26, 2006
448 F3d 1357

Headnotes

PATENTS

[1] Patentability/Validity — Specification — Enablement (▶115.1105)

Patent applications from which senior party in interference derives priority adequately enable poxvirus-based vaccine corresponding to count, even though applications describe vaccine vectors in general and focus on "subgenus" of herpesviruses, since applications discuss poxvirus invention in at least three passages, specifically mention "vaccinia virus," and state that claimed invention can be applied to any virus in which "essential" gene or genes can be identified and deleted from or inactivated within virus genome, since differences between herpesvirus and poxviruses were well known in art, which would have aided person of ordinary skill in application of herpesvirus example in construction of poxvirus vaccines, and since parties stipulated to high level of skill in art, and person of ordinary skill would clearly have possessed knowledge of DNA sequence of poxvirus genome and locations of "essential regions" thereon.

[2] Patentability/Validity — Specification — Written description (▶115.1103)

Examples are not necessary to support adequacy of written description, provided patent specification otherwise provides sufficient information to convince person of ordinary skill in art that inventor possessed claimed invention, since specification is written for person of ordinary skill, who reads patent with knowledge of what has come before; in present case, absence of examples involving poxviruses in applications from which senior party in interference derives priority does not render written description inadequate to support senior party's claim to poxvirus-based vaccine corresponding to count.

[3] Patentability/Validity — Date of invention — Reduction to practice (▶115.0405)

Patentability/Validity — Specification — Written description (▶115.1103)

Actual reduction to practice is not required for satisfaction of written description requirement, even though reduction to practice is ordinarily best evidence that invention is complete, since it does not follow that proof of reduction to practice is necessary in every case, and to extent written description requires showing of "possession of the invention,"said invention can be "complete" even if actual reduction to practice is absent; in present case, fact that senior party in interference had not actually produced poxvirus-based vaccine corresponding to count is not dispositive of issue of whether senior party's applications satisfy written description requirement.

[4] Patentability/Validity — Specification — Written description (▶115.1103)

There is no per se rule that, if claim limitation is directed to macromolecular sequence, specification must

always recite gene or sequence, regardless of whether it is known in prior art; in present case, applications from which senior party in interference derives priority satisfy written description requirement for poxvirus-based vaccine corresponding to count, even though specifications do not describe

"essential regions" of any poxvirus or incorporate by reference any literature that described DNA sequence of poxvirus genome and locations of "essential regions," since accessible literature sources clearly provided, as of relevant date, genes and their nucleotide sequences, and satisfaction of written description requirement therefore does not require either recitation of genes and sequences, or their incorporation by reference.

Particular Patents

Particular patents — Chemical — Poxvirus-based vaccine

5,770,212, Falkner, Holzer, and Dorner, recombinant poxviruses with foreign DNA in essential regions, judgment holding inventors not entitled to claims corresponding to count in interference no. 105,187 affirmed.

Case History and Disposition

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent interference between Falko-Gunter Falkner, Georg Holzer, and Friedrich Dorner, junior party (patent no. 5,770,212), and Stephen C. Inglis, Michael E.G. Boursnell, and Anthony C. Minson, senior party (application no. 08/459,040). Junior party appeals from entry of final judgment against it on sole count in interference. Affirmed.

Attorneys

John P. Isacson and Paul M. Booth, of Heller Ehrman, Washington, D.C., for appellants.

Robert G. McMorrow Jr., of Connolly Bove Lodge & Hutz, Wilmington, Del., for appellee.

Judge

Before Gajarsa, circuit judge, Archer, senior circuit judge, and Dyk, circuit judge.

Opinion Text

Opinion By:

Gajarsa, J.

This is an appeal from a decision of the Board of Patent Appeals and Interferences("Board") in Interference No. 105,187, declared on December 24, 2003, between Falkner *et al.*, U.S. Patent No. 5,770,212 ("the Falkner '212 patent") and Inglis *et al.*, U.S. Application Serial No. 08/459,040 ("the Inglis '040 application"). The Administrative Patent Judge (APJ) designated Inglis as the senior party. On December 29, 2004, the Board issued a final decision, holding that Falkner could not antedate Inglis' September 25, 1990 priority date, and entered judgment against Falkner on the sole count of the interference. It ordered that Falkner was not entitled to claims 1-19 of the Falkner '212 patent. It further ordered that Inglis was entitled to claims 9, 10, 29 and 30 of the '040 application. Falkner filed a timely notice of appeal. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § § 141 and 142. For the reasons discussed below, we affirm the judgment of the Board.

I. BACKGROUND

A. The Invention

Some vaccines against a virus (the "target virus") incorporate harmless fragments of the target virus's genetic material into a second virus, called a "viral vector." When a person is vaccinated, the viral vector produces harmless fragments of the target virus, ultimately conferring immunity against it. To prevent the viral vector from itself causing a harmful infection in the inoculee, it must be attenuated. Attenuation is achieved by deleting or inactivating one or more genes responsible for the vector's growth and infectiousness. However, because the vaccine is produced by essentially "growing"the vector virus (accompanied by its inserted target virus gene), attenuation makes it difficult to manufacture the vaccine. The traditional solution to this problem has been to inactivate genes known as "inessential"genes. With inessential genes inactivated, the viral vector is substantially less pathogenic. At the same time, because the vector virus can still fully reproduce itself, albeit more slowly, the vaccine can be produced in commercial quantities. However, the traditional approach carried a disadvantage, namely the risk that the vector virus, though attenuated, could still cause a harmful infection in the inoculee.

The inventors discovered a way of making vaccines safer by deleting or inactivating an *essential*, rather than an inessential, gene from the viral vector's genome, while at the same time solving the production problem by growing the vaccines in cells that were complementarily modified to produce the absent essential viral gene product "on behalf of" the vector virus. Thus, the modified vector virus could be readily grown in these complementarily-modified cells, but not in other cells, such as those of an inoculee.

This approach is applicable to many different kinds of vector viruses, e.g., adenoviruses, herpesviruses, poxviruses and retroviruses. The subject matter of this interference, however, is directed specifically to vaccines in which the vector virus is a *poxvirus*. For many vector viruses, there is a risk that vectors that have been attenuated in essential genes can

"swap"genes with the host cell genome, thereby reacquiring their deleted genes and reverting to wild-type virus. This risk can be minimized through the use of viruses that are "cytoplasmic", meaning that they are unlikely to enter the cell nucleus. Because a cell's genes are located in the nucleus, cytoplasmic viruses such as poxvirus cannot swap genes with the cell genome and possibly revert to a virulent wild-type virus.

B. Defining the Count and Assigning Priority

The sole count of the interference was either "[a] vaccine according to Claim 1 of Falkner's 5,770,212 patent or a vaccine according to Claim 29 of Inglis' 08/459,040 application." Claim 29 of the Inglis '040 application reads:

> A vaccine comprising a pharmaceutically acceptable excipient and an effective immunizing amount of a mutant virus, wherein said mutant virus is a mutant *poxvirus* and has a genome which has an inactivating mutation in a viral gene, said viral gene being essential for the production of infectious new virus particles, wherein said mutant virus is able to cause production of infectious new virus particles in a complementing host cell gene expressing a gene which complements said essential viral gene, but is unable to cause production of infectious new virus particles when said mutant virus infects a host cell other than a complementing host cell; for prophylactic or therapeutic use in generating an immune response in a subject.

(emphasis added)

Claim 1 of the Falkner '212 patent reads:

> A vaccine comprising (a) a defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus, wherein(i) said defective poxvirus comprises a DNA polynucleotide encoding an

antigen and said DNA polynucleotide is under transcriptional control of a promoter, and (ii) the function can be complemented by a complementing source; and (b)a pharmaceutically acceptable carrier.

The Administrative Patent Judge (APJ) designated claims 1-19 of the Falkner '212 patent and claims 9,10, 29, and 30 of the Inglis '040 application as corresponding to the interference count.[1] Both parties sought the benefit of earlier-filed applications to establish dates of constructive reduction to practice.[2] The ALJ accorded the Inglis '040 application (filed June 2, 1995) the benefit of several earlier-filed applications, dating back to September 25, 1990.[3] Likewise, the APJ accorded the Falkner '212 patent (issued June 23, 1998 from an application filed February 21, 1997)the benefit of earlier-filed applications, but

these dated back only to April 29, 1994.[4] Consequently, the APJ designated Inglis as the senior party.

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[1] Inglis's claim 29 is his broadest claim, directed to poxvirus; and claim 30, which depends on claim 29, is a poxvirus vaccine for mammalian subjects. Claim 9 is directed to poxvirus but contains some additional limitations unrelated to the type of virus used; claim 10 depends on claim 9 and is directed to a single species of poxvirus, namely vaccinia virus. Falkner's claims 2-10 depend on claim 1. Falkner claim 10 is directed to a method of producing the vaccine of claim 1, and the remaining method claims depend thereon.

[2] Priority in an interference goes to the first to invent, but a rebuttable presumption exists that the inventors made their inventions in the chronological order of their effective filing dates, namely that the senior party invented first, *see* 37 C.F.R. § 1.657(a) (2004), and the junior party bears the burden of proving otherwise, *see* § 1.657(b), such as by proving that she actually reduced the invention to practice before the constructive filing date (priority date) of the senior party, or that she was first to conceive and diligently reduced the invention to practice, starting from a date prior to reduction to practice by the senior party. *See* 35 U.S.C. § 112(g) (2000). Falkner sought to rely, in part, on an alleged date of conception and beginning of reasonable diligence: April 27, 1994.

On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly chose to decide the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. *See Singh v. Brake*, 222 F.3d 1362, 1371 [55 USPQ2d 1673](Fed. Cir. 2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests).

[3] The Inglis priority applications were U.S. Application Serial No. 08/384,963 ("the Inglis '963 application"), filed February 7, 1995; U.S. Application Serial No. 08/030,073 ("the Inglis '073 application"), filed May 20, 1993; WO/92/05263, PCT/GB91/01632 ("the Inglis PCT application"), filed September 23, 1991, published in English on April 2, 1992; GB 9104903.1("the Inglis 1991 British application"), filed March 8, 1991;and GB 9020799.4 ("the Inglis 1990 British application"), filed September 25, 1990. The Inglis '040 application is a continuation in part of the '963 application, which was in turn a continuation of the Inglis '073 application. The '073 application corresponded to the Inglis PCT application. The Inglis PCT application claimed priority to, and was essentially identical to, the Inglis 1990 and 1991 British applications.

[4] The Falkner priority applications were U.S. Application Serial No. 08/616,313 ("the Falkner '313 application") filed March 14, 1996; and U.S. application Serial No. 08/235,392 ("the Faulkner '392 application"), filed April 29, 1994.

C. Board Decision

The specifications of all of Inglis' earlier applications were similar. Although they focused on herpesvirus vectors, they contained several passages related to poxvirus-based vaccines. Because Falkner believed that these passages did not adequately describe and enable the poxvirus invention, he challenged both Inglis' entitlement to priority as to the count and the patentability of Inglis' corresponding claims. Falkner

brought these challenges in three closely-related preliminary motions before the Board. In each, as the moving party, Falkner carried the burden of proof by a preponderance of the evidence. *See* 37 C.F.R. § 1.637(a); *see also Kubota v. Shibuya*, 999 F.2d 517, 520 n.2 [27 USPQ2d 1418] (Fed. Cir. 1993) (explaining that "[t]he term 'burden of proof' ... means the burden to establish the proposition at issue by a preponderance of the evidence").

Falkner brought his first preliminary motion pursuant to 37 C.F.R. § 1.633(a),[5] arguing that the claims in Inglis's involved ('040) application that corresponded to the count were unpatentable because they failed to meet the written description requirement of 35 U.S.C. § 112. In support of his argument, he stated, *inter alia*, that (1) the specification of Inglis's '040 application did not identify any essential genes in poxvirus or describe the inactivation of such genes, (2) vaccines based on vaccinia (a type of poxvirus)had not yet been produced, and (3) the bulk of the Inglis specification was directed not to poxviruses but to herpesviruses. The Board denied Falkner's motion, based in part on his failure to address the perceived shortcomings of the '040 claims in light of the specification.

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[5] On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly decided the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. *See Singh v. Brake*, 222 F.3d 1362, 1371 [55 USPQ2d 1673](Fed. Cir. 2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests); *see also Brown v. Barbacid*, 436 F.3d 1376, 1379 n.1 [77 USPQ2d 1848] (Fed. Cir. 2006) (holding that the Board did not err in applying the old rules "under which this case was decided").

Second, Falkner moved pursuant to 37 C.F.R. § § 1.633(g) & 1.637(g) to deny Inglis the priority benefit of his earlier applications, arguing that they did not sufficiently describe and enable the claims in question.[6] Falkner argued that without the benefit of these applications Inglis would be unable to establish constructive reduction to practice earlier than Falkner. Falkner would win priority as to the count, and Inglis'corresponding claims would be unpatentable. In support of his motion, Falkner alleged deficiencies in Inglis' benefit specifications similar to those raised in his first motion. The Board carefully articulated the legal standard, correctly explaining that "benefit with respect to priority in an interference is granted with respect to *counts* not *claims*"and that "[a]ll that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count." *Board Op.* at 7 (citing *Hunt v. Treppschuh*, 523 F.2d 1386, 1389 [187 USPQ 426] (CCPA 1975) (holding that where a "parent application is relied upon as a prior constructive reduction to practice[,] .... the § 112, first paragraph requirements need only be met for an embodiment within the count")). After careful review of the record, the Board held that Falkner had failed to meet his burden of proof.

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[6] Falkner did not argue lack of enablement with respect to the Inglis '963 patent because he believed that the teachings of the Falkner '392 patent, filed in 1994, would have enabled the subsequent '963 patent.

Third, Falkner moved for judgment pursuant to 37 C.F.R. § 1.633(a) that the claims in Inglis' involved ('040) application that corresponded to the count were anticipated and therefore unpatentable. He argued that because Inglis' earlier applications had failed to adequately describe and enable the *full scope* of his current claims, the current claims could not be accorded the benefit of 35 U.S.C. § 120 for the purpose of antedating patent-defeating prior art.[7] The Board explained that 35 U.S.C. § § 119 & 120 require benefit applications to comply with § 112, first paragraph, with respect to the *full scope* of what a party now claims,

rather than with respect to merely one embodiment within the scope of the interference count. After carefully considering the

written description and enablement issues, the Board denied the motion. As a result of the denial of Falkner's several motions, Inglis remained the senior party, and the Board ordered judgment as to the subject matter of the count in favor of Inglis.

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[7] Here, Falkner points to his own U.S. Pat. No. 5,766,882 ("the '882 patent'), issued in March 1995, as the patent-defeating prior art.

D. Issue and Standard of Review

On appeal, Falkner essentially reiterates the arguments that he made before the Board. While we recognize that each of these three arguments is distinct, they are nonetheless all related, and under the facts of this particular case, we need only to resolve the following common issue: whether the Inglis benefit applications adequately describe and enable a poxvirus-based vaccine. Falkner also argues that the Board committed other errors, such as initially designating Inglis as the senior party and failing to afford Falkner an opportunity for briefing prior to making this designation. These arguments lack merit, and we shall not further discuss them. We turn, therefore, to the central issues in this case: written description and enablement.

Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 [19 USPQ2d 1111] (Fed. Cir. 1991). Enablement is a question of law involving underlying factual inquiries. *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 [42 USPQ2d 1001] (Fed. Cir. 1997); *see also In re Wands*, 858 F.2d 731, 737 [8 USPQ2d 1400] (Fed. Cir. 1988)(holding that whether undue experimentation is required is a "conclusion reached by weighing many factual considerations... . includ[ing] (1)the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

This court applies the standards of the Administrative Procedure Act ("APA")in reviewing decisions of the Board. *See Dickinson v. Zurko*, 527 U.S. 150, 152 [50 USPQ2d 1930] (1999) (holding that 5 U.S.C. § 706 governs our review of PTO appeals). Accordingly, we will set aside actions of the Board if they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and we set aside factual findings that are unsupported by substantial evidence. *See In re McDaniel*, 293 F.3d 1379, 1382[63 USPQ2d 1462](Fed. Cir. 2002) (citing 5 U.S.C. § 706); *see also In re Sullivan*, 362 F.3d 1324, 1326 [70 USPQ2d 1145] (Fed. Cir. 2004) (substantial evidence review of factual findings). We review questions of law *de novo*. *See Rapoport v. Dement*, 254 F.3d 1053, 1058 [59 USPQ2d 1215] (Fed. Cir. 2001).

Substantial evidence is defined as that which a reasonable person might accept as adequate to support a conclusion. *See In re Zurko*, 258 F.3d 1379, 1384[59 USPQ2d 1693](Fed. Cir. 2001). It requires an examination of the record as a whole, taking into account both the evidence that justifies and detracts from an agency's opinion. *See In re Gartside*, 203 F.3d 1305, 1312 [53 USPQ2d 1769] (Fed. Cir. 2000). An agency decision can be supported by substantial evidence, even where the record will support several reasonable but contradictory conclusions. *See id.*; *see also In re Jolley*, 308 F.3d 1317, 1320 [64 USPQ2d 1901] (Fed. Cir. 2002).

II. DISCUSSION

A. Contents of the Inglis Priority

Applications

The claims that correspond to the count of the interference are directed to a novel type of vaccine that is comprised of a "vector virus" in the poxvirus family. Conceptually, poxviruses are a "subgenus"of viruses that includes the "species" vaccinia. All of the prior Falkner applications described poxvirus vaccine vectors in detail, and to the exclusion of other types of vaccine vectors (e.g., herpesvirus vaccine vectors). These applications provided five detailed working examples regarding the preparation and use of vaccines from defective poxviruses. They also described the use of a particular species of poxvirus vaccine vector, namely vaccinia virus.

In contrast, the Inglis applications described vaccine vectors in general, and then focused on the subgenus of herpesviruses, for which they provided a detailed example. Nevertheless, at least three passages discussed the poxvirus invention and specifically mentioned "vaccinia virus."[8] For example, after introducing the concept of vaccine vectors, the

Page 1006

specification states that "[t]ypically members of the pox virus family, e.g. vaccinia virus, are used as vaccine vectors."[9] The specification later discusses the deletion of essential genes from vaccine vector genomes, noting that the "invention can be applied to *any virus* where one or more essential gene(s)can be identified and deleted from or inactivated within the virus genome"(emphasis added). Moreover, it provides that "the virus may comprise an orthopox virus, for example, vaccinia virus, which may comprise a heterologous sequence encoding an immunogen derived from a pathogen." Finally, it reads:

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[8] We recognize that the Inglis applications do not describe any actual reduction to practice of a poxvirus vaccine. *See Carroll Declaration* (stating that the '040 application did not contain any discussion of the "actual creation of the recited 'mutant poxvirus'" and that the application in fact stated "that a vaccinia virus with a deletion in an essential gene had not been produced."). As we discuss below, however, an actual reduction to practice is unnecessary to satisfy the written description requirement.

[9] Because of the substantial similarity in the specifications of all of the Inglis benefit applications, we shall refer in this opinion to representative passages from the earliest of the applications, the Inglis 1990 British application.

> For example vaccinia virus, a poxvirus, can carry and express genes from various pathogens, and it has been demonstrated that these form effective vaccines when used in animal experimental systems. The potential for use in humans is vast, but because of the known side effects associated with the widespread use of vaccinia as a vaccine against smallpox, there is reluctance to use an unmodified vaccine in humans. There have been attempts to attenuate vaccinia virus by deleting non-essential genes such as the vaccinia growth factor gene... However, such attenuated viruses can still replicate in vivo, albeit at a reduced level. No vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine.

The application provides a detailed example of an embodiment that comprised not a poxvirus, but a *herpesvirus*, including the identity of the deleted essential sequences therein. Nevertheless, for the reasons discussed below, we find no error in the Board's determinations on the adequacy of written description and enablement in the various Inglis disclosures.

B. Enablement

Because the adequacy of the disclosure is judged from the perspective of one of ordinary skill in the art, we

start our review of the Board's decision by noting that the parties stipulated to a high level of skill in the art. They defined the skilled artisan as having 5-10 years experience creating recombinant poxvirus, as being familiar with the poxvirus literature, the use of poxvirus as a vector for the expression of heterologous genes, and having the "needed technical skill to practice the experimentation described in the scientific literature relating to recombinant virus, including poxvirus." The Board agreed with the parties' stipulation as to level of skill.

The Board did not err in finding Inglis' claims to be enabled as a matter of law, in light of its articulated underlying factual findings. In support of its conclusion, it noted that "there is extensive disclosure of the selection of an essential gene, its deletion or inactivation and the production of a mutated virus with said deleted or inactivated gene, albeit for herpesvirus."Moreover, because the differences between the herpesviruses and poxviruses were well known, this would have aided the person of ordinary skill in the art in her application of the lessons of the herpesvirus example in the construction of poxvirus vaccines. The Board observed that "the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue'in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation." Thus, the Board found the Inglis applications to be enabling.

[1] Reviewing the Board's legal conclusion of enablement, as based on its underlying findings of fact, we cannot say that the Board erred. With respect to a skilled artisan's ability to identify "essential"poxvirus genes, as discussed below we note that there was undisputed testimony that as of the time of filing of the earliest Inglis application publications in professional journals had disclosed the DNA sequence of the poxvirus genome along with the locations of the "essential regions." The person of ordinary skill in the art would clearly have possessed such knowledge, and given the ready accessibility of the journals, the absence of incorporation by reference is not problematic. Indeed, "[a] patent need not teach, and preferably omits, what is well known in the art." *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 [3 USPQ2d 1737] (Fed. Cir. 1987).

C. Written Description

On appeal to this court, Falkner essentially reargues the positions on written description

that he took before the Board. Although the Board erred in its articulation of the written description standard, that error is harmless. The Board held that "an actual possession standard is *not* required." (emphasis added). But our precedent clearly establishes that "[t]he applicant must ... convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 [19 USPQ2d 1111] (Fed. Cir. 1991). Nonetheless, we conclude there is no need for remand because the undisputed testimony supports the Board's ultimate conclusion.

As noted above, the Board found several passages in the Inglis '040 application(and in the benefit applications) that were directed to poxvirus. No length requirement exists for a disclosure to adequately describe an invention. *See In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1534 [25 USPQ2d 1241](Fed. Cir. 1992) ("[T]he adequacy of the description of an invention depends on its content in relation to the particular invention, not its length."). Furthermore, the testimony of Inglis' expert, Dr. Boursnell, established that the articles describing essential genes for poxvirus were well-known in the art. Dr. Boursnell testified that "the skilled person would have been readily able to choose an essential vaccinia gene" based on references that have been publicly available since 1990. The testimony of Falkner's expert, Dr. Carroll, did not refute this claim.

The parties also dispute several aspects of our law of written description, which we now address. We conclude that the Board applied correct law. Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a

biological macromolecule must contain a recitation of known structure.

1. Examples Are Not Required

[2] First, it is clear that the absence of examples involving poxviruses in the Inglis applications does not render the written description inadequate. As we explained in *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*:

> A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005) (citing *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 [54 USPQ2d 1227] (Fed. Cir. 2000); *In re GPAC Inc.*, 57 F.3d 1573, 1579 [35 USPQ2d 1116] (Fed. Cir. 1995)).

2. Actual Reduction to Practice Is Not Required

[3] As we explained in *Capon v. Eshhar*, "[t]he 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." 418 F.3d 1349, 1357 [76 USPQ2d 1078](Fed. Cir. 2005). The Board was correct, however, not to view as dispositive that Inglis had not actually *produced* a poxvirus vaccine,[10] because an actual reduction to practice is not required for written description.[11] *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 [69 USPQ2d 1886] (Fed. Cir. 2004) ("We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice.

Constructive reduction to practice is an established method of disclosure ... ."). *Rochester*, moreover, is consistent with Supreme Court precedent. In the context of interpreting 35 U.S.C. § 102(b), the Court held that "[t]he word 'invention'must refer to a concept that is complete, rather than merely one that is 'substantially complete.'" *Pfaff v. Wells Elecs.*, 525 U.S. 55, 66[48 USPQ2d 1641](1998). It then proceeded to make clear that although "reduction to practice ordinarily provides the best evidence that an *invention* is complete... . it does not follow that proof of reduction to practice is necessary in every case." *Id.* (emphasis added).[12] Thus, to the extent that written description requires a showing of "possession of the *invention*," *Capon*, 418 F.3d at 1357 (emphasis added), *Pfaff* makes clear that an invention can be "complete" even where an *actual* reduction to practice is absent.[13] The logical predicate of "possession"is, of course, "completeness."

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[10] The Inglis specifications stated that "[n]o vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine."

[11] The Board believed that Falkner's expert, Dr. Carroll, had premised his opinions on the misunderstanding that actual reduction to practice was required to prove written description, and it discredited his expert opinion.

[12] Similarly, this court has carefully explained the relationship between written description and possession, explaining that a showing of possession is not necessarily sufficient to demonstrate the adequacy of written

description. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 [63 USPQ2d 1609](Fed. Cir. 2002) ("[P]roof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, P 1. As with 'possession,' proof of a reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification.").

[13] In contrast to reduction to practice, conception *is* a prerequisite to an adequate written description. *See Fiers v. Sugano*, 984 F.2d 1164, 1171 [25 USPQ2d 1601] (Fed. Cir. 1993) ("[O]ne cannot describe what one has not conceived.").

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3. Recitation of Known Structure Is Not Required

[4] Falkner argues, *inter alia*, that the Inglis specifications do not adequately describe the poxvirus invention, in light of *Eli Lilly*, because they do not describe the "essential regions" of any poxvirus. 119 F.3d 1559. We note, in addition, that Inglis did not attempt to incorporate by reference any literature that described the DNA sequence of the poxvirus genome and the locations of the "essential regions." However, it is the binding precedent of this court that *Eli Lilly* does *not* set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. *See Capon*, 418 F.3d at 1357 ("None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., *Regents v. Lilly*, *Fiers v. Revel*, *Amgen*, or *Enzo Biochem*, require a re-description of what was already known."). Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh." *Id.* at 1358. Rather, we explained that:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Id. at 1357.

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in *Capon*, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." *Id.* at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference[14]

(where permitted)of such genes and sequences.

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[14] Here, the patentee did not attempt incorporation by reference. Where, of course, certain material that is not present in the specification is deemed nonessential to the satisfaction of the written description requirement, the issue of proper incorporation by reference *vel non* is irrelevant.

In conclusion, having reviewed the decision of the Board, we can discern no error in its conclusion that the disclosures relied upon by Inglis for priority purposes adequately described and enabled the invention directed to poxvirus, there being substantial evidence to support these findings. Consequently, we hold that the Board's award of priority to Inglis was proper.

AFFIRMED

No costs.

- End of Case -